

## REMARKS

The application was originally filed with 34 claims, namely, claims 1-34. By this paper, claims 27-34 are cancelled for being directed to a non-elected claim group. More specifically, during a telephone conversation with the Examiner on February 26, 2007, the undersigned provisionally elected Group I claims, claims 1-26, to prosecute in this application. That election is hereby affirmed. Hence, claims 27-34 are being cancelled for having been withdrawn from further consideration.

As to the prior art, claims 1-26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Jugenheimer et al., U.S. Publication No. 2002/0062130. The rejection and the cited art have been carefully reviewed and considered. By virtue of amendments made to independent claims 1 and 14, it is respectfully submitted that the invention as defined by these claims is clearly distinguished over Jugenheimer. Favorable reconsideration of these claims and the claims that depend therefrom is respectfully requested.

In accordance with various aspects of the invention, the invention relates to a gastric reduction device, system, and method that provides for transesophageal formation of a gastric reduction pouch of the stomach. The device includes an expandable structure which may be placed in a stomach and expanded to occupy a fractional volume of the stomach. An evacuator is then fed through the expandable structure and utilized to deflate the stomach and draw the stomach to and around the expandable structure to form the gastric reduction pouch. A fastener is then pushed through the expandable structure and deployed for securing an annular fold of the stomach adjacent the expandable structure to maintain the gastric reduction pouch.

Jugenheimer, in contrast, relates to a device, system, and method for deploying a surgical clip. The clip, when deployed, forms a pair of jaws that pinch tissue together. The clip is said to be useful for preventing hemorrhaging at a surgical site as by closing, for example, organ perforations. The clip is deployed by being pushed off of the end of an endoscope by a balloon as the balloon is inflated. The endoscope tip may have a lumen therein for drawing a vacuum to pull tissue to be clipped to the tip of the endoscope.

As may be noted, independent claims 1 and 14 have been amended. Claim 1 has been amended to call for a gastric reduction device comprising an expandable structure, placeable in a stomach, the expandable structure, when expanded, occupying a portion of the stomach, an evacuator that deflates the stomach around the expandable structure to form a gastric reduction pouch, and the further limitation of a fastener that secures an annular fold of the stomach adjacent the expanded expandable structure to maintain the gastric reduction pouch.

It is respectfully submitted that Jugenheimer fails to show, describe, or even suggest the device defined in claim 1. More specifically, Jugenheimer does not show or describe a fastener capable of providing an annular fold of tissue as claimed. In contrast, Jugenheimer merely provides a clip that pinches tissue. The clip is formed by a pair of jaws which bite tissue over a localized area to prevent bleeding, for example. Nowhere is a clip shown or described that secures an annular fold as claimed.

Claim 14 has been amended to define a gastric reduction system comprising an expandable structure, placeable in a stomach, and, when expanded, occupying a fractional volume of the stomach, an evacuator that deflates the stomach and draws the stomach to and around the expandable structure to form a gastric reduction pouch with stomach tissue, a fastener that is operable to maintain the gastric reduction pouch, and the additional limitation of a pusher, separate from the expandable structure, that pushes the fastener into a deployed position to maintain the gastric reduction pouch.

In Jugenheimer, a balloon is used to push the clip off of the end of an endoscope. The balloon pushes the clip as the balloon is expanded. As defined in claim 14, an expandable structure is utilized to occupy a fractional volume of the stomach and to form the gastric reduction pouch when the evacuator deflates the stomach. A pusher, separate from the expandable structure, pushes the fastener into a deployed position to maintain the gastric reduction pouch. This structure is nowhere shown, described, or even suggested in Jugenheimer.

Accordingly, from the foregoing, it is respectfully submitted that the amendments made to claims 1 and 14 clearly distinguish the invention defined by these claims over Jugenheimer. Accordingly, it is respectfully submitted that the 35 U.S.C. § 102(b)

rejection of these claims has been overcome, and that these claims are in condition for allowance. Such action is earnestly solicited.

In view of the allowability of claims 1 and 14, it is respectfully submitted that claims 2-13 which are dependent from claim 1, and claims 15-26 which depend from claim 14 are also allowable for the same reasons. With regard to the dependent claims, claims 9 and 10 have been amended to correct claim dependency, claims 7, 11, 12, 14, and 25 have been amended to correct an inadvertent antecedent informality, and claim 8 has been amended to further define the evacuator recited in claim 1. More specifically, claim 8 now recites that the evacuator extends through the expandable structure, that the fasteners carried on the evacuator, and that the device further comprises a pusher that pushes the fastener through the expandable member. Allowance of all of the dependent claims is respectfully requested.

Lastly, by this paper, new claims 35-46 have been added to the application. Claim 35 is in independent form.

It is respectfully submitted that new independent claim 35 is patentably distinguishable from Jugenheimer since Jugenheimer does not disclose or suggest a fastener "having an axial passageway surrounded by the annual fold of the stomach, the axial passageway permitting ingested food to pass out of the gastric reduction pouch." Jugenheimer is directed to a device which is directed to a clip which is used to close an opening and, as such, it is respectfully submitted that Jugenheimer clearly does not disclose or suggest a fastener having an "axial passageway" as claimed.

Applicants further submit that it would not have been obvious to provide Jugenheimer with the claimed axial passageway since Jugenheimer is concerned with closing openings with the clip rather than creating or providing an opening in the clip. To this end, Jugenheimer draws tissue toward an end cap and uses the clip to secure this tissue together. Nowhere does Jugenheimer disclose or suggest providing an axial passageway and it is respectfully submitted that it would not have been obvious to do so. The foregoing comment also applies equally to claims 1 and 14 as amended.

New claims 36-46 depend from claim 35. In view of the allowability of claim 35 as demonstrated above, allowance of new dependent claims 35-46 is respectfully requested.

### **CONCLUSION**

In view of the foregoing, it is respectfully submitted that all claims are in condition for allowance.

In the event additional fees are due as a result of this response, payment for those fees has been enclosed in the form of a check. Should further payment be required to cover such fees you are hereby authorized to charge such payment to Deposit Account No. 07-1897.

If the Examiner believes that a phone interview would be helpful, he/she is respectfully requested to contact the Applicants' attorney, Richard O. Gray, Jr., at (425) 455-5575.

DATED this 6<sup>th</sup> day of June, 2007.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Richard O. Gray, Jr.", is written over a horizontal line.

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